IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Heno PERILLO et al.

Application No.: 10/580,651 — Confirmation No: 5789

Filed: November 29, 2006 — Art Unit: 1614

For: READY-FORUSE INJECTABLE SOLUTION OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE- 1H-PURIN-6(9H)-ONE, STERILE, STABLE; CLOSED SYSTEM FOR PACKING THE SOLUTION, PROCESS FOR ELIMINATING ALKALINE RESIDUALS OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6 (9H)-ONE CRYSTALS; PHARMACEUTICAL PRESENTATION AS A CLOSED SYSTEM READY-FOR-USE; USES AND METHODS — Examiner: Finn, M.R.

Honorable Commissioner of Patents and Trademarks
Washington, DC, 20231

DECLARATTON UNDER 37 C.F.R. § 1.132

Sir:

I, Mr. Heno Perillo, a citizen of Brazil and residing at Rua L 53, Edifício Pitangueiras, Setor Oeste, Goiânia, GO, Brazil, say and declare as follows:

1. I was the state head manager of Brazilian Legion of Attendance – LBA; Pharmacy Professor at Federal University of Goiás; Department in charge at the University of Goias, Staff President of courses at Federal University of Goiás; President of the Council of Curators at Federal University of Goiás from 1971 to 1973; Founder of Pharmacy Council of the state of Goiás, Registration n. 03; Counselor of Pharmacy Council of Goiás; Member of the Commission which elaborated the Legislation for the General Governance of Federal University of Goiás (Port. N. 00160-71) of the

Magnificent Dean; Technical director of HALEX ISTAR PHARMACEUTICAL INDUSTRY LTDA and Member of the National Academy of Pharmacy. Besides of all these pharmaceutical activities:

2. I have worked as Fiscal counselor at, Federation of Industries of Goiás State from 2005 to 2008.

3. I have worked as President at, Trade Union of Chemical and Pharmaceutical Industries of Goiás State from 1988 to 2004.

4. I have worked as Vice-President at, Federation of Industries of Goiás State from 2002 to 2005.
5. I am Council Supervisor Member for Developmental Bank of Goiás State (B.D.-Goaiás).

6. I have worked as President at, Commercial and Industrial Association for Goiás State from 1975 to 1976.

7. I have worked as President at, Council for the Commercial Learning Center of Goiás State (SENAC) from 1965 to 1968.

8. I have worked as President at, Council for Social Service Trading (SESC) of Goiás State from 1965 to 1968.

9. I was Member of Brazilian Delegation for the 52nd International Labor Organization Meeting held in Geneva – Switzerland in 1968.

10. I have worked as Vice-President at, Commercial and Industrial Association of Goiás State from 1973 to 1974.

11. I was Member of the Administration Council of the Bank of the State of Goiás State from 1970 to 1974.

12. I was Member of Fiscal Council of the Bank of the State of Coiás from 1965 to 1970.

13. I have worked as President at, Trading Federation of the State of Goiás from 1965 to 1968.

14. I am one of the inventors in U.S. Serial Number 10/580,651 and I am very familiar with the subject matter thereof and have been researching the subject matter thereof since 2000.

15. I have performed, commissioned or supervised the performance of the experiments described in the following paragraphs in support of patentability of the above-identified patent application.

16. The attached report shows that the product of the present application is a major advancement over the state of the art at the time the invention was made. The report presents the facts that:

- the gangcyclovir formulation of the invention is stable,
- the formulation is adequate to be wrapped in a closed system of a sterile plastic package,
- the formulation itself is sterile,
- the formulation has a neutral pH appropriate for packaging in a closed system with glucose or sodium solution, and
- the formulation is ready to use, requiring no manipulation by the user.

DRN/MHE/cjd

17. At the time the present invention was made, a manufacturer of the state of the art producing lyophilized gancyclovir would recommend that the administration of sodium gancyclovir in compatibility with solution infusion should be stocked under refrigeration. In contrast, the product of the present invention does not need refrigeration.

18. At the time the present invention was made, the state of the art was such that one administering gangcyclovir reconstituted a manufacturer's lyophilized gancyclovir powder with sterile water for injection and diluted the resulting solution in sodium chloride 0.9% in a PVC package. Such reconstituted formulation is physically and chemically stable for 14 days when stocked under refrigeration at 5 °C. However because of the absence of antimicrobials preservatives, it is recommended that the reconstituted formulation be used within 24 hours. Also the pH of the reconstituted formulation would be from 9 to 11.

19. In contrast, the present invention in a closed system does not have preservatives and it is sterile and with proven stability for 24 months stocked at ambient temperature (20-30 °C). Such stability would be unexpected to one of ordinary skill in the art who reads the Smith, Harris and Mueller references cited by the Examiner.

20. Furthermore, this stability is achieved by the invention by changing the type of crystal form of the gancyclovir obtained by a process, e.g. as recited in the present claim 47, that eliminates alkalines otherwise present in gangcyclovir crystals prepared according to the state of the art at the time the present invention was made.

21. The undersigned declares further that all statement made herein of his own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or

DRN/MHE/cjd

both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of above identified application or any patent issuing thereon.

Mr. Heno Perillo

Date 09/06/2010

Attachments:
- Report entitled "Physico-Chemical and Thermoanalytical Characterization of Gancyclovir Samples"